

ART UNIT: 1643

Lisa Rasmussen

EXAMINER: Blanchard, Daivd J.

|fW

Application of

: Subhashis Banerjee et al.

Serial No.

: 10/622,210

Filed

: July 18, 2003

Entitled

: TREATMENT OF

VASCULITIDES USING TNFALPHA INHIBITORS

Attorney Docket No. BBC-207

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

CERTIFICATE OF MAILING

The undersigned hereby certifies that this correspondence is being deposited with the U.S. Postal Service as First Class Mail, in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.

August 29, 2006

date of mailing and signature

TRANSMITTAL LETTER

Sir/Madam:

Transmitted herewith are: [X] Change of Attorney Docket Number and Change of Correspondence Address; [X] An Information Disclosure Statement under 37 CFR §§ 1.56, 1.97 and 1.98; [X] Form PTO-1449 Information Disclosure Statement; [X] A photocopy of each reference cited; and [X] An Acknowledgement Postcard; to be filed in the above-identified patent application.

FEE FOR ADDITIONAL CLAIMS

[X] A fee for additional claims is not required.

[] A fee for additional claims is required. The additional fee has been calculated as shown below:

		CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	NUMBER OF EXCESS CLAIMS	RATE		FEES DUE	
	TOTAL CLAIMS	· -	29	0	× \$50	=	0.00	٦
,	INDEPENDENT		11	0	×\$200	=	0.00	7
	FIRST INTRODUCTION OF MULT. DEPENDENT CLAIM + \$360						0.00]
	TOTAL FEES DU	E				=	00.00	

PETITION FOR EXTENSION OF TIME

[]	Extension is requested under 37 CFR 1.136(a), and the following extension fee is applicable for the
	paper(s) filed herewith: [] \$120.00 for response within first month pursuant to 37 CFR 1.17(a)(1);
	[] \$450.00 for response within second month pursuant to 37 CFR 1.17(a)(2);
	[] \$1020.00 for response within third month pursuant to 37 CFR 1.17(a)(3);
	[] \$1,590.00 for response within fourth month pursuant to 37 CFR 1.17(a)(4).
	[] \$2,160.00 for response within fifth month pursuant to 37 CFR 1.17(a)(5).

[X] The Commissioner is hereby authorized to charge payment of any additional fees required in connection with the paper(s) transmitted herewith, or to credit any overpayment of same, to **Deposit Account No.**010025. A duplicate copy of this transmittal letter is transmitted herewith.

Respectfully submitted,

Tara Seshadri, Ph.D.

Agent for Applicant Registration No. 48,591

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(508) 688-8110



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Date

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§§ 1.56, 1.97 AND 1.98

Sir/Madam:

In accordance with the duty of disclosure under 37 CFR § 1.56, Applicants submit this Information Disclosure Statement pursuant to 37 CFR §§ 1.97 and 1.98 for the above-identified application. Applicants makes the following publications of record in the above-identified application.

U.S. Patent Documents

Le et al., August 12, 1997, U.S. Patent No. 5,656,272

Foreign Patent Documents

Shenoy et al., September 19, 2002, WO 02/072636

Other Publications

Barron et al., J. Rheumatology, (1999); 26(1): 170-190.

Blank et al., Clin. Exp. Immunol., (1995); 102: 120-130.

Brahn et al., Clin. Immunol., (1999); 90(1): 147-151.

Brouwer et al., J. Exp. Med., (1993); 177: 905-914.

Churg, A., Mod. Pathol., (2001); 14(12): 1284-1293.

Cotch, M.F., Curr. Opin. Rheumatol., (2000); 12: 20-23.

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Fraga et al., Curr. Rheumatol. Rep., (2002); 4: 30-38.

Francis, G.E., Focus on Growth Factors. (1992); 3: 4-10.

Gedalia, A., Curr. Rheumatol. Rep., (2002); 4: 25-29.

Gross, W.L., Curr. Opin. Rheumatol., (2002); 14: 11-14.

Grunebaum et al., Clin. Exp. Immunol., (2002); 130: 233-240.

Harman et al., Survey of Ophthalmology, (1998); 42(5): 458-480.

Hirata et al., Acta. Otolaryngol. Suppl., (1993); 503: 79-81.

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Kobayashi et al., Intern. Med. (2002); 41(1): 44-46.

Lehman et al., Arthritis & Rheum. (1985); 28(6): 652-659.

Marquez et al., Curr. Rheumatol. Rep. (2003); 5: 128-135.

Marzi et al., Shock, (1995); 3(1): 27-33.

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Old, L., Science, (1985); 230: 630-632.

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Sfikakis et al., Ann. Rheum. Dis., (2002); 61: ii51-ii53.

Silman et al., Lancet, (1990); 335: 1078-1080.

Sneller, M.C., Cleve. Clin. J. Med., (2002); 69: SII40- SII43.

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Sundel, R.P., Curr. Rheumatol. Rep., (2002); 4: 474-482.

Tomer et al., Arthritis & Rheum. (1995); 38(10): 1375-1381.

Uddhammar et al., Brit. J. Rheumatol., (1998); 37: 766-769.

Williams et al., Proc. Natl. Acadd.Sci. USA., (1992); 89: 9784-9788.

Form PTO-1449 listing each of these documents and photocopies of each document are enclosed herewith for the Examiner's convenience.

This paper is being mailed before the mailing of a first Office action. Pursuant to 37 CFR §1.97(b)(4), no fee is required with this submission.

Applicant does not intend to represent that any of the documents submitted herein is material prior art to this invention or that the list represents an exhaustive search of documents related to this invention.

Applicant respectfully requests that the documents submitted herein be considered and made of record in this application.

Respectfully submitted,

Tara Seshadri, Ph.D.
Agent for Applicant
Registration No. 48,591
Abbott Bioresearch Center
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Worcester, MA 01605-4314 Telephone: (508) 688-8058 Telefax: (508) 688-8110

PTO/SB/08A (07-05)

Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449/PTO

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INFORMATION DISC STATEMENT BY APPE

(Use as many sheets as necessary)

of

Col	inpiete ii Kriowii	`
Application Number	10/622,210	
Filing Date	July 18, 2003	
First Named Inventor	Subhashis Banerjee	
Art Unit	1643	
Examiner Name	David J. Blanchard	
Attornov Docket Number	DDC 207	

Complete if Known

U. S. PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ^{2 (# known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear			
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	1	^{US-} 5,656,272	08-07-1997	Le et al.				
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Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	T
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)	MM-DD-YYYY		Or Relevant Figures Appear	T
	2	WO 02/072636	09-19-2002	Altus Biologics Inc.		
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Signature		Considered		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the Emperor must precede the serial number of the patent document. **Nind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. **Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

	te for form 1449/PTO			Complete if Known		
				Application Number	10/622,210	
			CLOSURE	Filing Date	July 18, 2003	
STATEMENT BY APPLICANT			PPLICANT	First Named Inventor	Subhashis Banerjee	
(Use as many sheets as necessary)				Art Unit	1643	
, , , , , , , , , , , , , , , , , , , ,				Examiner Name	David J. Blanchard	
Sheet	2	of	5	Attorney Docket Number	BBC-207	

		NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²	
	3	Barron et al., "Report of the National Institutes of Health Workshop on Kawasaki Disease", J. Rheumatology, (1999); 26(1): 170-190.		
	4	Blank et al., "Immunization with anti-neutrophil cytoplasmic antibody (ANCA) induces the production of mouse ANCA and perivascular lymphocyte infiltration", Clin. Exp. Immunol., (1995); 102: 120-130.		
Brahn et al., "Suppression of coronary vasculitis in a murine model of Kawasak Disease using an angiogenesis inhibitor", Clin. Immunol., (1999); 90(1): 147-15				
Brouwer et al., "Antimyeloperoxidase-associated proliferative glomerulonephritis: an animal model", J. Exp. Med., (1993); 177: 905-91				
	7	Churg, A., "Recent advances in the diagnosis of Chrug-Strauss Syndrome", Mod. Pathol., (2001); 14(12): 1284-1293.		
	8	Cotch, M.F., "The socioeconomic impact of vasculitis", Curr. Opin. Rheumatol., (2000); 12: 20-23.		
	9	Damianovich et al., "Pathogenic role of anti-endothelial cell antibodies in vasculitis", J. Immunol., (1996); 156: 4946-4951.	· 5-	
	10	Deguchi et al., "Enhanced expression of the tumour necrosis facto/cachectin gene in peripheral blood mononuclear cells from patients with systemic vasculitis", Clin. Exp. Immunol., (1990); 81: 311-314.		
	11	Deguchi et al., "Enhanced transcription of TNF in systemic vasculitis", Lancet, (1989); 2: 745-746.		
	12	DiGirolamo et al., "Expression of TNF-a by human plasma cells in chronic inflammation", J. of Leukocyte Biology, (1997); 61: 667-678.		

Examiner	Date	
Signature	Considered	•

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Coodina				Application Number	10/622,210		
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	13	Dogan et al., "Sindromul Behcet", Oftalmologia, (2002); 52: 23-30.	
	14	Duong et al., "Superantigenic activity is responsible for induction of coronary arteritis in mice: an animal model of Kawasaki disease", Int. Immunol., (2002); 15(1); 79-89.	
	15	Fraga et al., "Takayasu's Artheritis", Curr. Rheumatol. Rep., (2002); 4: 30-38.	
	16	Francis, G.E., "Protein modification and fusion proteins", Focus on Growth Factors. (1992); 3: 4-10	
	17	Gedalia, A., "Kawasaki Disease: an update", Curr. Rheumatol. Rep., (2002); 4: 25-29.	
	18	Gross, W.L., "Churg-Strauss syndrome: update on recent developments", Curr. Opin. Rheumatol., (2002); 14: 11-14.	
	19	Grunebaum et al., "The role of anti-endothelial cell antibodies in Kawasaki disease – in vitro and in vivo studies", Clin. Exp. Immunol., (2002); 130: 233-240.	
	20	Harman et al., "Experimental Vestibular Neuritis Induced by Herpes Simplex Virus", Survey of Ophthalmology, (1998); 42(5): 458-480.	
	21	Hirata et al., "Wegener's Granulomatosis", Acta. Otolaryngol. Suppl., (1993); 503: 79-81.	
	22	Hoffman et al., "Wegener's Granulomatosis", Arthritis & Rheum., (1998); 41(12): 2257-2262.	

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	23	Kaklamani et al., "Treatment of Behcet's Disease – an update", Semin. Arthritis Rheum., (2001); 30(5): 299-312.		
	24	Keffer et al., "Transgenic mice expressing human tumour necrosis factor: a predictive genetic model of arthritis", EMBO J., (1991); 10(13): 4025-4031.		
	25	Kinjoh et al., "Genetic selection for crescent formation yields mouse strain with rapidly progressive glomerulonephritis and small vessel vasculitis", Proc. Natl. Acad. Sci. USA, (1993); 90: 3413-3417.		
	- 26	Kobayashi et al., "Takayasu Arteritis", Intern. Med. (2002); 41(1): 44-46.		
	27	Lehman et al., "Coronary arteritis in mice following the systemic injection of group B lactobacillus casei cell walls in aqueous suspension", Arthritis & Rheum. (1985); 28(6): 652-659.		
	28	Marquez et al., "Granulomatous vasculitis", Curr. Rheumatol. Rep. (2003); 5: 128-135.		
	29	Marzi et al., "Effect of anti-tumor necrosis factor α on leukosyte adhesion in the liver after hemorrhagic shock: an intravital microscopic study in the rat", Shock, (1995); 3(1): 27-33.		
	30	Nose et al., "Arteritis in a novel congenic strain of mice derived from MRL/lpr lupus mice", Am. J. Path., (1996); 149(5): 1763-1769.		
	31	Old, L., "Tumor Necrosis Factor (TNF)", Science, (1985); 230: 630-632.		
	32	Schett et al., Obstruction of the pulmonary artery by granulomatous vasculitis: a clinical, morphological, and immunological analysis", Ann. Rheum. Dis., (2002); 61: 463-467.		

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PTO/SB/08B (07-05)
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Sheet 5 of 5	Attorney Docket Number	BBC-207		

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	33	Sfikakis et al., "Behcet's disease: a new target for anti-tumour necrosis factor treatment", Ann. Rheum. Dis., (2002); 61: ii51-ii53.	
	34	Silman et al., "Criteria for diagnosing Behcet's disease", Lancet, (1990); 335: 1078-1080.	
·	35	Sneller, M.C., "Granuloma formation, implications for the pathogenesis of vasculitis", Cleve. Clin. J. Med., (2002); 69: SII40- SII43.	
	36	Straub et al., "In polymyalgia rheumatica serum prolactin is positively correlated with the number of typical symptoms but not with typical inflammatory markers", Rheumatology(Oxford), (2002); 41: 423-429.	,
	37	Sundel, R.P., "Update on the treatment of Kawasaki disease in childhood", Curr. Rheumatol. Rep., (2002); 4: 474-482.	
	38	Tomer et al., "Characterization of biologically active antineutrophil cyctoplasmic antibodies induced in mice", Arthritis & Rheum. (1995); 38(10): 1375-1381.	
	39	Uddhammar et al., "Cytokines and adhesion molecules in patients with polymyalgia rheumatica", Brit. J. Rheumatol., (1998); 37: 766-769.	
	40	Williams et al., "Anti-tumor necrosis factor ameliorates joint disease in murine collagen-induced arthritis", Proc. Natl. Acadd.Sci. USA., (1992); 89: 9784-9788.	

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